

Pharmaceutical donations by the USA: an assessment of relevance and time-to-expiry

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This paper assesses the relevance and time-to-expiry of pharmaceutical donations by the USA by means of a convenience sample of two private voluntary organizations. Data were collected on 16 566 donations shipped between 1994 and 1997 for the two organizations to a total of 129 countries. For three field study countries (Armenia, Haiti, and the United Republic of Tanzania), between 37% and 65% of donated unique drug products were on the recipient countries' essential drugs lists, and between 50% and 80% were either on these lists or were permissible therapeutic alternatives. Between 10% and 42% were not listed on either the national essential drugs lists or the WHO Model List of Essential Drugs, nor were they permissible therapeutic alternatives. For the worldwide data set, the median times to expiry when shipment by the organizations took place were 599 and 550 days; about 30% of shipment items had a year or less of shelf-life, and about 6% had less than 100 days of shelf-life. Although a majority of the donations fulfilled the criteria of relevance and time-to-expiry, a substantial proportion failed to do so. Actions are proposed with a view to improving the relevance and time-to-expiry of USA pharmaceutical donations.

Voir page 679 le résumé en français. En la página 680 figura un resumen en español.

Background

International donors of pharmaceutical products have been criticized for providing unsuitable items. Published accounts relate to earthquakes in Mexico (1) and Armenia (2), the war in Sudan (3, 4), and the Russian Federation since 1990 (5). Between 50% and 60% of medical supplies donated to Bosnia and Herzegovina in the period 1992–96 were reportedly inappropriate (6). Various methods have been used to assess appropriateness, and reports have focused more on practices during disaster relief than on those associated with development aid.

WHO and other major international agencies active in humanitarian emergency relief have identified six main problems associated with drug donations (Table 1) and proposed 12 guidelines for improving the positive impacts associated with such donations (7). The document divides the guidelines into four categories:

- selection of drugs;
- quality assurance and shelf-life;
- presentation, packing and labelling;
- information and management.

Examples were given of problems connected with drug donations, mostly relating to single incidents and often to disaster relief, but no data were provided on the frequency of these problems. No systematic assessment of donated pharmaceuticals appears to have been carried out.

We have assessed drug donations in which US pharmaceutical companies and private voluntary organizations were involved. The study included:

- classification of donated drugs;
- quantitative analysis of a data set of worldwide donations;
- assessment of donation policies of companies and private voluntary organizations;
- field studies in three countries (8).

This article reports some of the results from the classification and quantitative analysis investigations, and particular attention is given to the problems of relevance and time-to-expiry of donated drugs.

Methods

Data sources

We obtained data on all products shipped worldwide from 1994 to 1997 by two private voluntary organizations based in the USA. These organizations, which requested anonymity, were not selected randomly but were proposed by the study's sponsors since they handle large quantities of donated drugs on a regular basis. They have been ranked according to in-kind contribution among the top 10 of 54 such

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Table 1. **Six problems associated with drug donations**

- Donated drugs often are not relevant to the situation of the recipient.
- Many donated drugs arrive unsorted and inappropriately labelled.
- The quality of donated drugs does not always comply with standards in the donor countries (including expired drugs, drugs returned from patients, or free samples).
- Donor agencies sometimes ignore local administrative procedures.
- Donated drugs may have a high declared value, based on the market value in the donor country, leading to high customs charges for recipients.
- Drugs may be donated in incorrect quantities, creating disposal problems.

Source: see ref. 7.

bodies working with pharmaceuticals or medical supplies (with a range of US\$ 23 million to US\$ 138 million of in-kind contributions for the top ten). In 1995 they represented 16% of the total value of in-kind contributions for all 54 organizations (about US\$ 830 million, including pharmaceutical and other in-kind contributions) (9).

Since the data relating to the private voluntary organizations covered product donations other than drugs, we excluded all medical supplies (such as needles, syringes, bandages and dressings) and consumer goods (such as non-medicated shampoos, diapers and dehydrated soup). We used the First Data Bank's national drug classification software (10) to aggregate drug donations into categories based on chemical entity and therapeutic class. The link between the private voluntary organization files and the First Data Bank files allowed us to verify the package size (number of unit doses per package) for a unique national drug classification and the physical form of the product (tablets, injection, etc.). From the linked file we retrieved brand and generic names for a unique national drug classification. We converted all names to generic names in order to compare the data relating to the private voluntary organizations with national essential drugs lists and the WHO Model List of Essential Drugs (subsequently referred to as the WHO Model List).

For one private voluntary organization (designated "A") the data set covered the period from January 1994 to May 1996, and for the other (designated "B") the period from July 1994 to June 1997. The "cleaned" data set had 11 321 line items of donated drugs for organization A, sent to 117 recipient countries in a total of 1017 shipments; for organization B there were 5245 line items of donated drugs sent to 67 recipient countries in a total of 1597 shipments. The combined data set included 129 countries. Organization B had data on the length of time that donated products were held in its warehouses.

Relevance of donated drugs

We assessed the relevance of donated drugs for a subset of the private voluntary organization database, namely all products sent to Armenia, Haiti, and the United Republic of Tanzania, where field studies were conducted. We developed a classification system based on essential drugs list status (11, 12), in accordance with the second of the guidelines (7) referred to above: "All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List, unless specifically requested otherwise by the recipient". National essential drugs lists, which are modelled on the WHO Model List, include drugs that are considered appropriate for local disease patterns and circumstances of care. We used the 1995 edition of the WHO Model List, which includes the provision of therapeutic alternatives for 108 drugs that represent a therapeutic class, allowing alternative unlisted drugs from the correct pharmacological categories to be substituted. Substitution is not acceptable for the remaining 196 drugs (11). We applied the WHO Model List provision for therapeutic alternatives to the three national essential drugs lists on the basis that such alternatives can be relevant as they apply to local conditions.

The drugs shipped to each of the three study countries (in the data set) were placed in one of the following categories:

- drugs on the country's essential drugs list;
- drugs in a therapeutic category of the national essential drugs list and constituting a permissible therapeutic alternative according to the WHO Model List;
- drugs not in the first two categories but on the WHO Model List;
- drugs not in any of the three previous categories (non-list drugs).

For our analysis of relevance, we defined a *unique drug product* as a particular drug in a particular dosage form and strength, without regard to package size. We compared each drug shipped with the national essential drugs list and the WHO Model List. A unique drug product was classified as in the country essential drugs list or the WHO Model List if the drug in the same dosage form was listed for the same indication, without regard to strength. Each unique drug product was counted once, no matter how many times the same product was shipped. This analysis was limited to Armenia, Haiti, and the United Republic of Tanzania because we had access to their national essential drugs lists and because of the time required for:

- constructing the list of unique drug products for each country and each private voluntary organization;
- comparing the list with the national essential drugs lists and the WHO Model List;
- comparing it with the therapeutic categories of the national essential drugs lists and the therapeutic

groups allowing alternatives according to the WHO Model List.

Time-to-expiry of donated drugs

The sixth guideline (7) states: "After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year". We defined a *shipment item* as one donated drug product in a particular dosage form, strength and package size which was listed on the private voluntary organization's shipment list as a line item. Each shipment item of a given drug product was counted separately. A *shipment* was defined as all the shipment items sent by a private voluntary organization on the same date.

We analysed the entire data set for all 129 countries relating to the number of days between the date of expiry and the date of shipment by the private voluntary organization (shelf-life). We then calculated the mean, median, distribution by quartiles, and proportions with less than one year and less than 100 days until expiry.

Results

Relevance of donated drugs

Between 37% and 65% of unique drug products were listed on the three countries' essential drugs lists, and between 50% and 80% were either on the essential drugs lists or were permissible therapeutic alternatives, according to our application of the WHO Model List provisions to these lists (Table 2). Of the remaining products in the database, between 1% and 15% were on the 1995 WHO Model List and between 10% and 42% belonged to category four. The χ^2 test for the data shown in Table 2 comparing the four drug categories by country, for both private voluntary organizations combined by country, revealed a significant difference between Armenia on the one hand and Haiti and the United Republic of Tanzania on the other (χ^2 test, 6 df = 27.20; $P < 0.001$).

Time-to-expiry of donated drugs

For all shipment items sent worldwide the median remaining times before expiry on shipment were 599 days and 550 days for private voluntary organizations A and B, respectively (Table 3). About 30% of the shipment items had a year or less of shelf-life remaining at the time of shipment (27.2% for A and 28.5% for B), and about 6% of all shipment items for both organizations had less than 100 days of shelf-life remaining on shipment (5.7% for A and 5.3% for B). For organization B the median interval between receipt of product and shipment to recipient countries was 113 days (warehousing time).

Discussion

This study provides the first systematic examination of patterns in US pharmaceutical donations for a large

Table 2. Donated drug products in four categories shipped to Armenia, Haiti, and the United Republic of Tanzania by two private voluntary organizations

	Armenia ^a		Haiti ^a		United Republic of Tanzania ^a	
	PVO A	PVO B	PVO A	PVO B	PVO A	PVO B
No. of unique drug products shipped ^b	164 (100) ^c	20 (100)	230 (100)	13 (100)	31 (100)	36 (100)
Category 1: Country EDL drugs ^d	75 (46)	13 (65)	85 (37)	6 (46)	12 (39)	14 (39)
Category 2: Therapeutic alternatives	46 (28)	3 (15)	35 (15)	3 (23)	7 (23)	4 (11)
Category 3: WHO ML drugs ^e	2 (1)	2 (10)	25 (11)	2 (15)	2 (6)	3 (8)
Category 4: Non-list drugs	41 (25)	2 (10)	85 (37)	2 (15)	10 (32)	15 (42)

^a PVO, private voluntary organization.

^b Pharmaceutical products that differ in active ingredient, dosage form and/or strength.

Note: Category 3 does not include products already counted in Categories 1 and 2, even if the products appear in the WHO ML.

^c Figures in parentheses are percentages.

^d EDL, essential drugs list.

^e WHO ML, World Health Organization Model List of Essential Drugs.

Table 3. Shelf-life at time of shipment by private voluntary organizations (shipment items for all countries)

	PVO A ^a	PVO B ^a
Total shipment items ^b	11 321	5 245
Mean shelf-life \pm SD at time of shipment (days)	655 \pm 213	571 \pm 186
Median (50th percentile) shelf-life at time of shipment (days)	599	550
% of shipment items with > 365 days	72.8	71.5
% of shipment items with \leq 365 days	27.2	28.5
% of shipment items with < 100 days	5.7 (649) ^c	5.3 (279)

^a PVO, private voluntary organization: data for PVO A for 117 countries; data for PVO B for 67 countries.

^b Shipment item is one donated drug product in a particular dosage form, strength and package size listed as a line item in the PVO's shipment list.

^c Figures in parentheses are the number of items.

data set from private voluntary organizations. A majority of drug donations met our criteria for relevance and time-to-expiry, but the study reveals a potential for problems in both of these areas, as expressed by the presence of category 4 drugs and by drugs shipped with a shelf-life of under a year.

Between 50% and 80% of donated drugs for the three countries in the study's private voluntary

organization database were either on the countries' essential drugs lists or were therapeutic alternatives for the drugs on these lists, i.e. in categories 1 and 2 in Table 2. If these categories are used to define the relevance of donations to local disease patterns and national pharmaceutical priorities, the results suggest that the majority of donated drugs in this sample were relevant. The proportion of relevant drugs is higher, ranging from 58% to 90% if drugs on the WHO Model List are included. Inclusion on this list, however, does not necessarily mean that a product is relevant for a particular country.

Table 2 shows a lower proportion of category 4 (non-list) drugs in Armenia than in Haiti and the United Republic of Tanzania for both private voluntary organizations. This could be a consequence of national policy decisions (the introduction of a national essential drugs list and a national drug policy, along with a central agency to review and approve donations), together with efforts by the organizations to comply with Armenian policies. However, the United Republic of Tanzania also has a national essential drugs list and a national drugs policy, although according to our field study the country's donation process is more decentralized. We cannot determine whether the apparently higher proportion of category 4 (non-list) drugs for the United Republic of Tanzania is due to pull factors (requests by recipients) or push factors (decisions on shipments by private voluntary organizations or donors).

Over half the shipment items in the private voluntary organization database had more than 500 days before expiry at the time of shipment. If shipment to the recipient countries were to take a month, these items would be delivered well within the standard period of a year to expiry on arrival (7).

The estimated median time that donated drugs were held by organization B was 113 days, which did not, on average, affect the quality of the products in terms of remaining time to expiry, since the median time to expiry at shipment from this organization was estimated to be 550 days. At the time of receipt by the organization, pharmaceutical products had an estimated median time to expiry of 663 days; after warehousing this was reduced to 550 days (using the measure of shipment items).

With regard to relevance, between 10% and 42% of the unique drug products shipped to the three countries were in category 4 (not on the countries' essential drugs lists, not therapeutic alternatives, and not on the WHO Model List). We were unable to determine whether these products were requested by the recipients; if they were, this would make them relevant according to guideline 2 (7). If not specifically requested, drugs shipped in category 4 could create various problems for the recipients.

With regard to time-to-expiry, about 30% of the shipment items had less than a year of shelf-life remaining at the time of shipment. These items did not meet the standard in guideline no. 6 (7) specifying a year of shelf-life on arrival in the recipient country, and could create disposal problems for the recipient,

depending on the shipment size and delays in customs and distribution. Items with shelf-lives of less than 100 days increase the risk of disposal problems.

We conducted a MEDLINE search covering the period 1966–98, using keywords associated with pharmaceutical donations (including developing countries, drug industry, drug storage, international cooperation, pharmaceutical preparations, relief work, and World Health Organization), and examined the bibliographies of articles published on drug donations. Two papers were identified which analysed a large sample of drug donations: one relating to an earthquake (2) and one to a war (6). There were also eight letters on specific incidents or countries (3, 4, 13–18), two news articles on countries (5, 19), and five papers on WHO policy or humanitarian aid agency policy (20–24). It is difficult to compare the results of our study with these published reports because the methods used to assess appropriateness are dissimilar or were not clearly defined in previous studies. The methods used in our study for evaluating relevance and time-to-expiry could provide the basis for a standard procedure for assessing the appropriateness of donated drugs.

Problems of drug donations may be more serious in disaster relief than in development aid. For example, 46% and 65% of the unique drug products shipped to Armenia by the two private voluntary organizations were listed on the country's essential drugs list and were therefore considered relevant. A study of the Armenian earthquake of 1988 found that only 42% of the donated drugs were considered relevant for the emergency situation (2). Our field study in Armenia suggests that the introduction of national pharmaceutical policies and agencies, together with efforts by private voluntary organizations to comply with Armenian policies, may have contributed to better performance under the conditions of development aid (25).

Guideline no. 2 (7) recommends that donated drugs be restricted to those on national essential drugs lists unless a national list is not available, in which case the WHO Model List should be used, or unless a specific request is made by the recipient. The structure of this guideline prompts the questions outlined below.

- Should a national essential drugs list, intended at least in part to guide cost-effective procurement decisions, be used as an exclusive list for product donations? In countries with limited prescribing information and limited prescriber expertise, this usage would be justified. In countries with good availability of information and expertise it seems reasonable to permit therapeutic alternatives and drugs not on essential drugs lists. If donations are restricted to drugs on such lists, patients with unusual medical problems and poor patients could be denied access to drugs not on essential drugs lists, possibly including more specialized therapies and more expensive and potentially more effective drugs.

- Who is the legitimate recipient of drug donations? A government and a nongovernmental agency may disagree over the appropriateness of a specific drug as a donation, because of different views about drugs that are not on an essential drugs list, therapeutic substitutes, or time before expiry. The guidelines (7) do not clearly define a recipient. A broad definition, including nongovernmental organizations, would expand the potential benefits of drug donations, especially in situations where governments are unstable or disputed and where nongovernmental organizations operate responsibly.
- How should tensions between health policy and industrial policy be resolved? Restricting donations to drugs on essential drugs lists could have unintended negative consequences from the perspective of industrial policy. Donations of such drugs could undermine retail sales of these products and could adversely affect local pharmaceutical production, which often begins with the generic products on a national essential drugs list. Similar unintended market consequences have arisen from donations of food aid (26). This matter should be addressed by national and international guidelines on drug donations.

It should be noted that our study did not measure the quantity of donated drugs (in terms of unit doses or tonnage), that it assessed only two aspects of the guidelines (7) related to relevance and time-to-expiry, and that it did not determine whether the sample of two private voluntary organizations was representative of the overall flow of drug donations from the USA. Future studies should deal with these issues. Nevertheless, the present article makes two important contributions: it provides the first public analysis of drug donations made by two major private voluntary organizations, and proposes a systematic method for assessing relevance and time-to-expiry.

We would like to address directly the study's sponsorship by a group of pharmaceutical companies and private voluntary organizations, because this could be cited as biasing the results (27). We selected the three countries for field studies of non-disaster circumstances in consultation with the sponsors in order to represent different geographical regions, countries where products from the USA have been received, and countries where private voluntary organizations from the USA have been working; we do not think that this selection significantly biased the results. The sponsors assisted in identifying the major private voluntary organizations that provided data for

the study; this could have created a positive bias, as noted above, if these organizations were more concerned about the relevance and time-to-expiry of donated drugs than other organizations.

On the other hand, without the full cooperation of the private voluntary organizations it would have been impossible to obtain the internal data on items shipped and to prepare the data for analysis. Overall, the sponsors agreed to make the study independent of drug donations. Consequently, this article was not reviewed by the sponsors prior to publication. Furthermore, if a positive selection bias exists our findings of potential problems with relevance and time-to-expiry indicate the need to improve the positive impact of donated drugs.

On the basis of our study we make the following recommendations.

- With regard to drug selection, the four categories for classifying drug donations should be used by participants in the donation process, in setting donation selection priorities and in assessing the relevance of drugs shipped.
- With regard to time-to-expiry, greater attention should be given to shelf-life by all organizations involved in drug donations. The number of shipment items with shelf-lives of under a year should be reduced, and for all products with such shelf-lives there should be explicit approval and written assurance from the recipients that the products will be used before expiry.
- Organizations involved in drug donations (both donors and recipients) should develop explicit policies that specify criteria for relevance and time-to-expiry. These policies should be open to public review and should require prior approval by recipients for drug items that do not meet the specified criteria for relevance and time-to-expiry. ■

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Résumé

Dons de produits pharmaceutiques effectués par les Etats-Unis d'Amérique : évaluation de leur adéquation et durée de conservation

Le présent article évalue l'adéquation et la durée de conservation des médicaments donnés par les Etats-Unis d'Amérique d'après un échantillon de commodité de

deux organisations bénévoles privées. Des données ont été recueillies sur 16 566 dons expédiés entre 1994 et 1997 par les deux organisations dans 129 pays au total.

Pour trois pays couverts par une étude de terrain (Arménie, Haïti et République-Unie de Tanzanie), 37 à 65% des médicaments particuliers donnés figuraient sur les listes de médicaments essentiels des pays bénéficiaires et 50 à 80% d'entre eux soit figuraient sur ces listes soit étaient des substituts thérapeutiques acceptables. Entre 10 et 42% ne figuraient ni sur les listes nationales de médicaments essentiels ni sur la Liste modèle des médicaments essentiels de l'OMS, et n'étaient pas non plus des substituts thérapeutiques acceptables. Au niveau mondial, la durée moyenne de conservation des

produits au moment de leur expédition par les organisations était de 599 et 550 jours; environ 30% des articles expédiés avaient une durée de conservation d'un an ou moins et quelque 6% avaient une durée de conservation inférieure à 100 jours. Si la majorité des dons remplissaient les conditions d'adéquation et de durée de conservation, tel n'était pas le cas d'une grande partie d'entre eux. Des mesures sont proposées pour améliorer l'adéquation et la durée de conservation des produits pharmaceutiques donnés par les États-Unis d'Amérique.

Resumen

Donaciones de medicamentos realizadas por los Estados Unidos de América: evaluación de la utilidad y la fecha de caducidad

Este artículo evalúa la utilidad y la fecha de caducidad de los medicamentos donados por los Estados Unidos a partir de una muestra de conveniencia de dos organizaciones de voluntarios privadas. Se reunieron datos sobre 16 566 donaciones que las dos organizaciones enviaron entre 1994 y 1997 a un total de 129 países. Para los tres países estudiados sobre el terreno (Armenia, Haití y la República Unida de Tanzania), entre un 37% y un 65% de los productos farmacéuticos donados figuraban en las listas de medicamentos esenciales de los países receptores, y entre un 50% y un 80% bien estaban incluidos en las listas, o bien eran alternativas terapéuticas admisibles. Entre un 10% y un 42% no figuraban ni en las listas nacionales de

medicamentos esenciales ni en la lista modelo de medicamentos esenciales de la OMS, y tampoco eran alternativas terapéuticas admisibles. En lo que respecta a los datos mundiales, los plazos medianos de expiración en el momento en que las organizaciones hicieron el envío fueron de 599 y 550 días; alrededor de un 30% de los artículos enviados tenían un tiempo de conservación de un año o menos, y cerca del 6% tenían un tiempo de conservación inferior a 100 días. Si bien la mayoría de las donaciones cumplían los requisitos en cuanto a utilidad y fecha de caducidad, una proporción sustancial no lo hacía. Se proponen medidas para mejorar la utilidad y el tiempo de conservación de los medicamentos donados por los Estados Unidos.

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